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<p>(54) Title: INCREMENTING MECHANISM IN PARTICULAR FOR USE WITH A MEMBRAL SYRINGE</p> <div data-bbox="316 1165 1307 1617"> </div> <p>(57) Abstract</p> <p>A mechanism for accurate dispensing of pre-set quantities of medicament from a syringe has a plunger (17) rotatable within a housing (13), which plunger (17) has a cam surface (19) engaged by a fixed follower (22) such that rotation of the plunger (17) moves the plunger away from the syringe. Internally within the plunger there is a number of parallel racks (40) each of which in turn comes into engagement with a first toothed wheel (47) on rotation of the plunger. The first toothed wheel (47) is connected to a second toothed wheel (48) which runs on a fixed rack (49) extending within the plunger parallel to the axis thereof. The first toothed wheel (47) is coupled to a thrust rod (44) for the piston (12) of the syringe. After pre-setting a required dose by rotation of the plunger (17), the plunger is then pushed towards the syringe, so rotating the first and second toothed wheels (47 and 48). This drives the thrust rod (44) into the syringe but by appropriate selection of the toothed wheel diameters and the tooth pitch thereof, an advantageous velocity ratio between the plunger and thrust rod movements may be obtained.</p>		

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INCREMENTING MECHANISM IN PARTICULAR FOR USE WITH A MEMBRAL SYRINGE

This invention relates to an incrementing mechanism for advancing a thrust member in response to advancement of an operating plunger. The invention in particular - but not exclusively - relates to an
5 incrementing mechanism adapted for use with a medical syringe, to permit the dispensing of a pre-set dose of medicament from a cartridge thereof.

In various engineering circumstances, a member is required to advance through a predetermined distance,
10 pre-selected to suit the application, and there have been numerous proposals for mechanisms aimed at achieving this. A particular problem exists in the case of the dispensing of a precise and predetermined quantity of medicament, from a syringe fitted with a
15 hypodermic needle by means of which the medicament is injected into a body. For example, in the case of the self-injection of insulin, there is a need for a simple and reliable device which may be pre-set to permit the precise dispensing of an accurately controlled quantity
20 of insulin upon depression of an operating member. Diabetes sufferers frequently have to effect such self-injections and it is highly convenient for them to have a self-contained device able to be used repeatedly to dispense successive quantities of insulin from a
25 cartridge thereof, the cartridge containing sufficient insulin for perhaps as many as ten separate injections, depending upon the quantity to be dispensed each time.

There have been several proposals for incrementing mechanisms specifically adapted for use with syringes
30 in order to permit the repeated dispensing of controlled doses of medicament. For example, in EP-A-0474839 one such mechanism is described. Though generally satisfactory, there is still a need for an incrementing mechanism which may be made even more
35 compact and so easy to use and readily carried in a

pocket or handbag, and yet which is able precisely to dispense relatively small quantities of medicament whilst still providing a significant movement of the operating plunger, to facilitate ease of use.

5 According to the present invention, there is provided an incrementing mechanism for advancing a thrust member in response to advancement of an operating plunger having a pre-set range of movement, in which mechanism the plunger is hollow and is formed
10 with an internal rack, the plunger being movable axially away from and towards a fixed abutment, the thrust member is slidably supported within the plunger and carries a first toothed wheel engaged with the rack, a second toothed wheel is coupled to the first
15 toothed wheel, and there is provided a fixed rack along which the second toothed wheel runs, the internal rack being disengageable from the first toothed wheel by rotation of the operating plunger whereafter the plunger may be moved away from the fixed abutment and
20 then on subsequent engagement of the internal rack with the first toothed wheel and driving of the plunger to engage the abutment, the thrust member is correspondingly advanced.

 Though it will be appreciated that the incrementing mechanism of the present invention may find
25 uses other than in connection with the dispensing of medicament from a syringe, that is the principal intended use of this mechanism and it will hereinafter be described solely with reference to that use.

30 When the incrementing mechanism of this invention is to be used to dispense a precisely measured dose from a syringe, the syringe is either pre-filled with medicament or is loaded with a pre-filled cartridge of the medicament whereafter the mechanism is then coupled
35 to the rear end of the syringe. The plunger is turned to disengage its rack from the first toothed wheel

associated with the thrust member and is moved axially rearwardly away from the abutment through a distance suitable for the dose to be dispensed. When the plunger has been turned to re-engage the rack with the first toothed wheel, the plunger is driven forwardly to re-engage the abutment. During this action, the first toothed wheel is rotated and so rotates the second toothed wheel which in turn runs along the fixed rack, so advancing the thrust member. By adjusting the relative diameters and numbers of teeth of the first and second toothed wheels, the velocity ratio (and so also the mechanical advantage) between the operating plunger and thrust member may be adjusted to give a manageable plunger movement for a relatively small thrust member movement for a typical dose to be dispensed. Conveniently, that velocity ratio may be set to be of the order of 4:1 whereby the thrust member moves through one quarter of the distance moved by the plunger, on any one operating stroke.

Most preferably, the operating plunger has a plurality of parallel axially-extending internal racks disposed in an equi-spaced manner around the internal surface of the plunger, with channels formed therebetween and in which may be positioned the first toothed wheel, upon rotation of the plunger. In this way, the toothed wheel may be engaged with any one of the racks in order to perform an operating stroke, and so with the plunger in any one of a number of different angular settings. Typically, five such racks may be provided.

Axial movement of the plunger away from the abutment, to pre-set a medicament dose to be dispensed, may be effected by drive means co-operating with the plunger upon the rotation thereof. Such drive means may include a cam surface on one of the plunger and a fixed component (such as a body of the mechanism) and a

cam follower on the other of the plunger and said fixed component. Preferably, the cam surface is configured to cause axial movement of the plunger only when the first toothed wheel is not engaged with the internal rack, or one of the internal racks, of the plunger. In this way, the toothed wheel - and also the thrust member - will not be moved axially as the plunger is moved axially away from the abutment.

In a preferred embodiment, the cam surface is formed externally of the plunger and is engaged by an axially-fixed resilient follower. For this arrangement, the cam follower may ride resiliently over the cam surface during axial movement of the plunger towards the abutment. Ramped ratchet teeth may be provided on the cam surface which ratchet teeth cooperate with and are aligned with the follower when the (or a) plunger rack is engaged with the first toothed wheel. The teeth serve to prevent axial movement of the plunger away from the abutment other than when driven by the cam surfaces, upon plunger rotation.

In order to permit the setting of a desired dose to be dispensed, the plunger preferably is formed with a series of index marks which successively are aligned with an indicator upon rotation of the plunger and its consequent movement away from the abutment. In a case where there is a plurality of racks formed internally within the plunger, the index marks are preferably formed in as many axial columns as there are racks and are arranged sequentially in a spiral manner around the plunger, so that successive index marks show at the indicator - which conveniently takes the form of a window through the mechanism body - as the plunger is rotated.

In the case of a syringe, it is most important that the operator is aware that the pre-set dose is dispensed. It should not therefore be possible for the

operator to pre-set a required dose which is for more medicament than remains in the syringe. To this end, limiting means may be provided to prevent pre-setting of the plunger to a position which, on the subsequent driving thereof to the abutment, would require the thrust member to move beyond its maximum advanced position, corresponding to the exhaustion of medicament from the syringe. This may be achieved by providing a nut coupled to the plunger for rotation therewith, but axially slidable with respect thereto, which nut is threadingly engageable with a fixed part of the assembly and which is then threaded along the fixed part upon plunger rotation until blocked against further movement by inter-engagement with the thrust rod. The nut then prevents further rotation of the plunger.

In order to prevent the thrust member moving axially when the first toothed wheel is disengaged from the plunger, a clutch may be formed between one of the toothed wheels and the thrust member to hold the wheels and so also the thrust member stationary other than when the plunger is driven towards the abutment.

In a preferred embodiment, where there is a plurality of racks formed in the plunger and a plurality of columns of staggered index marks only one of which is visible at a time through a window in a housing for the mechanism, there is provided a sleeve which surrounds at least part of the plunger and which obscures the window when in an initial position. Rotation of the plunger may release the sleeve to expose the zero mark only when the plunger has properly been aligned to initialise the mechanism. Thereafter, the indicated dose on further rotating the plunger will be the dose which will be dispensed upon subsequent actuation of the mechanism.

Rotation of the plunger may be performed by means of an external pre-setting knob, which is also used to effect axial driving movement of the plunger, to dispense medicament. Such a knob may be connected to the plunger through a slip-clutch, arranged to slip when the rotary force applied to the knob exceeds some predetermined value.

This invention extends to an incrementing mechanism of this invention as described above, in combination with a syringe for injecting a medicament, the mechanism being connected to the rear end of the syringe whereby doses of medicament may be dispensed by cycling the incrementing mechanism. The syringe may directly hold the medicament, or a cartridge of the medicament may be contained within the syringe. Either way, the medicament-dispensing piston of the syringe or cartridge is driven by the thrust member through a precisely controlled distance, upon cycling of the operating plunger.

By way of example only, one specific embodiment of incrementing mechanism constructed and arranged in accordance with the present invention will now be described in detail, reference being made to the accompanying drawings, in which:-

Figure 1 is a longitudinal sectional view through the incrementing mechanism, coupled to a syringe body containing a cartridge of medicament:

Figure 2 is a partially cut-away isometric view of the mechanism of Figure 1;

Figure 3 is a side view of the operating plunger of the mechanism;

Figures 4A and 4B are cross-sections through the mechanism on line IV-IV marked on Figure 1, with the operating plunger in two different angular settings;

Figure 5 is a detail view of the wheel assembly and support;

Figures 6A and 6B show the operation of a zero sleeve, in two different positions;

Figures 7A and 7B are respectively a cross-section through and a cut-away isometric view through the central part of the plunger and the co-operating part of the zero sleeve;

Figure 8 is an enlarged view of part of the plunger and the cam follower engageable therewith;

Figure 9 shows the operating button separated from the plunger;

Figure 10 shows the plunger in conjunction with a dose-limiting nut;

Figure 11 is a cross-section through the forward end of the plunger and the nut taken on line XI-XI marked on Figure 1; and

Figure 12 is an external view of a pen-like self-injection device incorporating the incrementing mechanism of Figures 1 to 11.

In the following description, the term "forward" refers to the direction of the needle-end of the syringe, and to the left in Figures 1 and 2; and the term "backward" refers to the direction away from the syringe, and so to the right in Figures 1 and 2.

The incrementing mechanism shown in the drawings is configured for use with a syringe including a housing 10 containing a cartridge 11 of a medicament, the cartridge having a dispensing piston 12 which, when moved axially along the cartridge 11, dispenses medicament therefrom, through a needle (not shown) at the forward end of the syringe housing. Such an arrangement is entirely conventional and forms no part of the present invention; it will not therefore be described further here.

The mechanism has a hollow body 13 in the forward end of which is provided a stop member 14 including an inwardly-directed rib 15 by means of which the body 13

may be mounted on the syringe housing 10, the rib 15 engaging in an external groove around that housing 10. Both rotatably and axially slidably mounted within the body 13 is an operating plunger 17 having formed along a forward portion 18 thereof columns of dose-indicating markings, and along a rearward portion thereof a cam surface 19 (see particularly Figures 3 and 8). A window 20 is formed in the body 13 to permit viewing of the index marks on the forward portion 18 of the plunger, an enlarging lens 21 being fitted in that window 20. The lens 21 is a part of a cam follower 22, which may resiliently engage with cams and ratchet teeth 24 formed on the cam surface 19. When so engaged, rotation of the plunger 17 in the appropriate sense will cause the plunger to move backward (rightwards in Figures 1 and 2) as the follower threads along the cams on the cam surface 19, so successively displaying the index marks through the window 20. Subsequently, the plunger may be thrust forward until its forward end engages radial face 23 of the stop member 14, the cam follower 22 riding over the ratchet teeth 24 of the cam surface 19 during this action. To allow this to occur, the ratchet teeth 24 are ramped (Figure 8), which teeth are arranged in five aligned columns, so that the plunger may be thrust forward only when follower 22 is aligned with one of the columns of teeth 24.

Slidably mounted within the housing 13, in the rearward part thereof, is a zero sleeve 25 (Figures 6A and 6B), the plunger 17 being rotatably received within the sleeve 25. A slot 26 is formed axially along the sleeve 25, arm 27 connecting lens 21 to the cam follower 22 extending along that slot and restraining the sleeve against rotation. The forward end of the sleeve is provided with a shutter blade 28 which obscures (Figure 6A) or opens (Figure 6B) the window 20

through the body 13, the index marks on portion 18 not being visible when the sleeve is in the position of Figure 6A.

At the forward end of the sleeve 25, there is an
5 inwardly-directed catch 29 (Figures 7A and 7B), the sleeve having axial slits to each side of the catch to allow outward springing thereof. An annular rib 30 (Figures 3, 7A and 7B) extends around the plunger 17 between the forward portion 18 and the cam surface 19,
10 the rib 30 having a notch 31 through which the catch may pass. A helical compression spring 32 acts between the forward end of sleeve 25 and an internal shoulder in the body 13, urging the sleeve to the right

The sleeve 25 may be moved to the left relative to
15 the plunger 17 by springing the catch 29 over the rib 30; the catch will then hold the sleeve in the position illustrated in Figure 6A and 7B, with the shutter blade 28 closing the window 20. Rotation of the sleeve 25 relative to the plunger 17 will bring the catch 29 into
20 alignment with the notch 31, whereby the sleeve may move to the position shown in Figure 6B under the action of spring 32.

An operating button 33 is engaged with the rearward end of the sleeve 25 by means of a rotatable
25 coupling 34. The button has two internal lugs 35 each of which has a projection 36, the projections 36 being slidably engaged in splines 37 formed at the rearward end of the plunger 17. The plunger will normally be driven by rotation of the button 33, but should the
30 torque applied to the button 33 exceed some predetermined value, then the button may rotate with respect to the plunger by the projections 36 springing inwardly to ride over the splines 37.

From the position of Figures 1 and 6A, rotation of
35 the button 33 will align catch 29 with notch 31, whereupon the button and sleeve 25 will move under the

action of spring 32 to the right until the catch engages the forward end of the cam surface 19, so moving shutter blade 28 to open the window 20. At the completion of an injecting stroke, on thrusting the button to the left, the sleeve will be moved back to its initial position with the catch 29 in front of the rib 30. The catch 29 and notch 31 are relatively disposed angularly so that when the catch passes rightward through the notch, opened window 20 is midway between the "0" and "1" index marks on the plunger. In this way, the displayed dose will always be the actual dose to be dispensed on leftward movement of the plunger.

The plunger 17 is formed internally with five axially-extending equi-spaced toothed racks 40, grooves 41 being formed between those racks. A support 42, formed integrally with stop member 14, is disposed within the plunger 17 and is held stationary with respect thereto, the racks 40 running on the outer surface of that support during plunger movement. A channel 43 is formed in the support 42, in which channel is slidably mounted a thrust rod 44 the forward end of which engages the piston 12 to cause axial movement thereof. The rearward end of the rod 44 defines a housing 45 having arcuate surfaces and within which is located a wheel assembly 46 including a first toothed wheel 47 which fits closely (but rotatably) to the arcuate surfaces of the housing 45. Formed integrally with the first toothed wheel is a second toothed wheel 48 engaged with a rack 49 formed on the support 42.

As the plunger 17 is rotated, the first toothed wheel 47 successively comes into engagement with each of the racks 40 formed in the plunger. Between each such engagement, the first toothed wheel 47 lies in a groove 41 of the plunger and so is free of the racks

40. The cam profile of the cam surface 19 is arranged so that upon rotation of the plunger, the plunger moves rearwardly only when the first toothed wheel 47 lies within a groove 41; whenever that toothed wheel 47 is engaged with a rack 40, no axial movement of the plunger takes place. The columns of ramped ratchet teeth 24 (Figures 3 and 8) are aligned with follower 22 when the toothed wheel 47 is so engaged, then to permit the forward movement of the plunger. In this way, rotation of the plunger will gradually also move the plunger to the right, whilst both the wheel assembly 46 and the thrust rod 44 remain stationary.

The cam surface 19 is shown in greater detail in Figure 8. Between the columns of ramped ratchet teeth 24 are formed individual cams 52 which, on being engaged by the cam follower 22, drive the plunger 17 axially, as the plunger is rotated. Each cam 52 is profiled to move the plunger through a suitable distance to dispense one dose unit, on thrusting the plunger to the left. The ratchet teeth serve to prevent an operator partially pushing the plunger to the left when the cam follower is aligned with a column of teeth 24, and then pulling the plunger back to continue rotation. Instead, once a forward push has started, the operator must push the plunger forward at least until the follower can re-engage in the next pitch of cams 52, nearer the front of the plunger, or the operator may push the plunger fully forwardly, and start again. Also, the ratchet teeth serve to prevent the plunger being moved out of the body 13 other than by being threaded, on being turned by button 33.

The ratchet tooth 53 at the end of the cam surface 19 is almost continuous and is of a greater height between the aligned columns of teeth 24. This tooth 53 is engaged by follower 22 when the mechanism is in its initial state as shown in Figures 1 and 6A, and

prevents the spring 32 pushing the plunger outwardly until the zero orientation has been selected.

From the foregoing description, it will be appreciated that the initial starting position for the mechanism is as shown in Figures 1, 2 and 6A, when a fresh cartridge has been inserted in the syringe housing. The button 33 is rotated until catch 29 passes through notch 31 in rib 30, under the action of spring 32, at which point the blade 28 exposes the plunger, mid-way between the "0" and "1" index marks. Continued rotation of the button 33 winds the plunger 17 to the right, both the wheel assembly 46 and the thrust rod 44 remaining stationary. The index marks are appropriately aligned with the racks 40, so that each time a selected dose is displayed, a rack is engaged with the first toothed wheel 47.

When the required dose has been set, the button 33 is thrust to the left, so driving the sleeve 25 to the left. The catch 29 engages rib 30 to drive the plunger to the left, the catch being restrained against outward movement by a co-operating rib within the body 13, until the left hand end of the plunger engages the radial face 23 of the stop member 14; then, the catch 29 comes free of the body rib and may spring outwardly and over rib 30. During this, the wheel assembly 46 is rotated by the action of the rack 40 on the first toothed wheel 47. The relative diameters of the first and second toothed wheels, and the pitch of the teeth, are selected such that the velocity ratio of the plunger movement to the rod movement is 4:1. This of course also gives a corresponding mechanical advantage.

It is important that the plunger 17 cannot be pre-set for dispensing a dose greater than that remaining available for dispensing. To that end, a limiting mechanism is provided for the plunger 17, as the thrust rod 44 approaches its extreme leftward (in Figure 1)

movement. This mechanism comprises a nut 55 (Figures 2, 10 and 11) having axial tines 56 frictionally engaged with corresponding splines formed internally within the forward end of the plunger 17; the nut 55 is in this way non-rotatably coupled to the plunger 17 but may slide axially with respect thereto. The nut 55 has an internal segmented thread 54, there being axial grooves through the thread in alignment with the tines 56. The forward end of the support 42 is of reduced diameter and is formed with a segmented screw-thread 57 co-operating with the segmented thread of the nut 55. The pitch of these co-operating threads is one quarter of the pitch of the cam surface 19, so that the nut moves rearwardly as the plunger is rotated to set a dose. On any given cycle, the rightward movement of the nut before thrusting the plunger to the left thus corresponds to the leftward movement of the rod 44, on driving the plunger into engagement with the radial face 23. A rib 58 is formed on the rod 44, and eventually a point is reached at which an abutment 59 on the nut 55 engages that rib 58 during plunger rotation to set a dose to be dispensed. This inhibits further plunger rotation, and the remaining deliverable dose then shows through the window 20. This dose may then be dispensed in the usual way, by thrusting the button 33 to the left. During each dispensing stroke, the nut 55 is moved back to its initial position with its end face against radial face 23, by interaction between the tines of the nut and the plunger.

After dispensing all medicament, the mechanism may be re-set by removing the spent cartridge and piston, turning the button 33 until the wheel assembly is free of racks 40 (Figure 4B) and then pushing the thrust rod back into the body 13. The mechanism is then ready for connecting to a fresh cartridge. In the alternative, the mechanism may be regarded as a non-reusable throw-

away item, further medicament being dispensed from a new cartridge connected to a new mechanism.

5 The above-described mechanism may be assembled into a pen-like housing, as shown in Figure 12. The cap 60 of the housing is removable to expose the syringe housing 10 and a hypodermic needle attached thereto, and to give access to the housing to permit the changing of the cartridge of medicament. When not in use, the cap is replaced and the complete assembly
10 may easily and conveniently be carried for use whenever required.

15 In an alternative arrangement (not shown), a cam follower separate from a pawl engageable with the ratchet teeth may be provided, the cam follower being specifically adapted to interact with the cams 52, and the pawl with the ratchet teeth. In this case, neither the pawl nor the cam follower need be arranged as a part of the lens; this has been done in the case of the described embodiment merely for convenience of
20 manufacture and assembly.

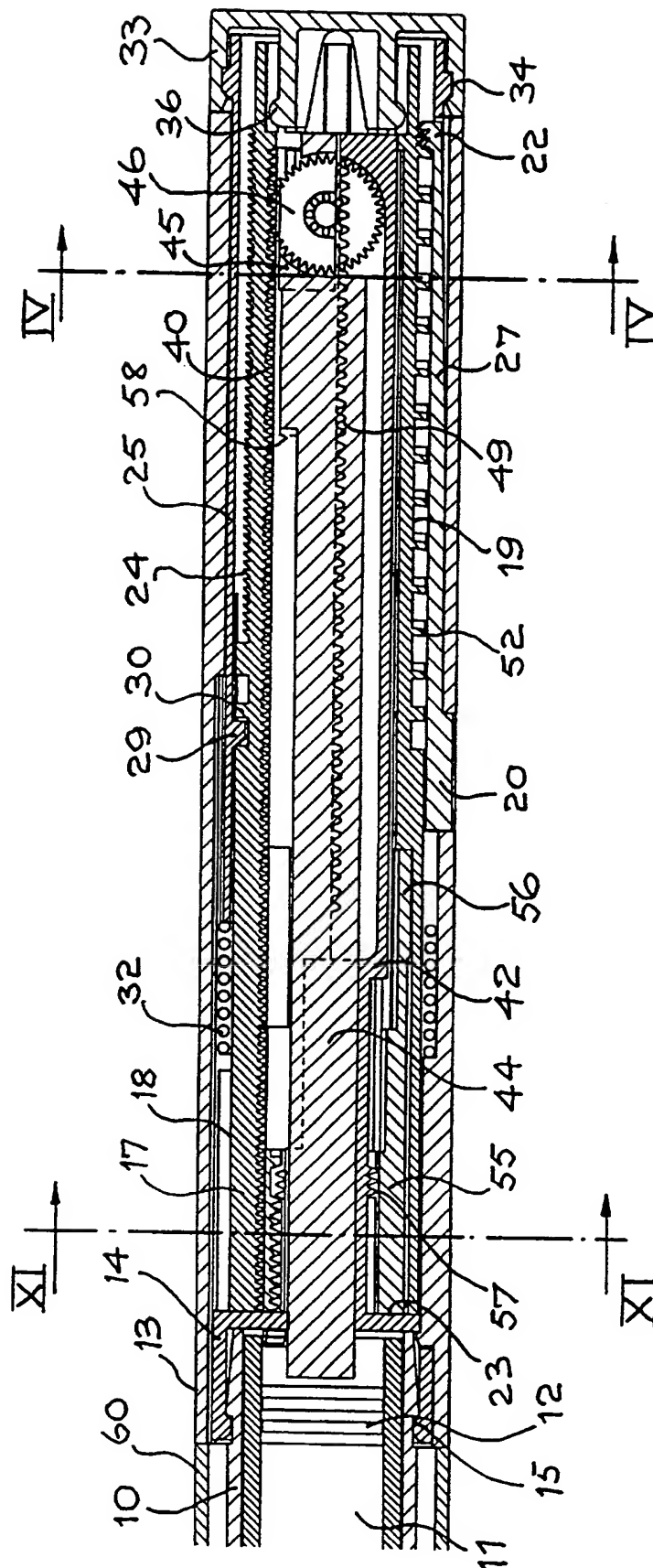
CLAIMS

1. An incrementing mechanism for advancing a thrust member in response to advancement of an operating plunger having a pre-set range of movement, in which mechanism the plunger is hollow and is formed with an internal rack, the plunger being movable away from and towards a fixed abutment, the operating rod is slidably supported within the plunger and carries a first toothed wheel engaged with the rack, a second toothed wheel is coupled to the first toothed wheel, and there is provided a fixed rack along which the second toothed wheel runs, the internal rack being disengagable from the first toothed wheel by rotation of the operating plunger whereafter the plunger may be moved away from the fixed abutment and then on subsequent engagement of the internal rack with the first toothed wheel and driving of the plunger to engage the abutment, the operating rod is correspondingly advanced.
2. An incrementing mechanism as claimed in claim 1, wherein the operating plunger has a plurality of internal racks formed along its internal surface and equi-spaced therearound, the first toothed wheel coming into and out of engagement with successive racks on rotation of the plunger.
3. An incrementing mechanism as claimed in claim 1 or claim 2, wherein there is provided drive means to effect axial movement of the plunger away from the abutment as the plunger is rotated, said drive means including a cam surface on one of the plunger and a fixed component and a cam follower on the other of the plunger and said fixed component.
4. An incrementing mechanism as claimed in claim 3, wherein the cam surface is configured to cause axial movement of the plunger only when the first toothed wheel is out of engagement with the or an internal rack of the plunger.

5. An incrementing mechanism as claimed in claim 3 or claim 4, wherein the cam surface is formed externally of the plunger and is engaged by an axially-fixed follower.
- 5 6. An incrementing mechanism as claimed in claim 5, wherein the follower is resiliently engaged with the cam surface and on axial movement of the plunger towards the abutment, the cam follower resiliently rides over the cam surface.
- 10 7. An incrementing mechanism as claimed in claim 5 or claim 6, wherein there is formed externally of the plunger a plurality of columns of ramped ratchet teeth, there being a like number of columns of teeth and internal racks within the plunger, which teeth co-
15 operate with the cam follower to prevent axial movement of the plunger away from the abutment.
8. An incrementing mechanism as claimed in any of claims 3 to 7, wherein the plunger is formed with a series of index marks which successively are aligned
20 with an indicator upon rotation of the plunger and its consequent movement away from the abutment.
9. An incrementing mechanism as claimed in claim 8, wherein there is provided a sleeve which surrounds at least part of the plunger and which obscures the index
25 marks on the plunger when in an initial position, rotation of the plunger releasing the sleeve to expose the zero index mark only when the plunger has properly been aligned to initialise the mechanism.
10. An incrementing mechanism as claimed in any of
30 claims 3 to 9, wherein the total maximum advancement of the thrust member is limited, and limiting means are provided to prevent pre-setting of the plunger to a position which, on the subsequent driving thereof to the abutment, would require the thrust member to move
35 beyond its maximum advanced position.

11. An incrementing mechanism as claimed in claim 10, wherein the limiting means comprises a nut coupled to the plunger for rotation therewith but axially slidable with respect thereto, which nut is threadingly engageable with a part of the mechanism to move the nut away from the abutment during plunger rotation, the thrust member eventually engaging said nut when said member is advanced towards its maximum advanced position, thereby to block further plunger rotation.
12. An incrementing mechanism as claimed in any of the preceding claims, wherein the first and second toothed wheels are co-axial and directly coupled one to the other.
13. An incrementing mechanism as claimed in claim 12, wherein there are two second toothed wheels, one to each side of the first toothed wheel and engageable with respective fixed racks.
14. An incrementing mechanism as claimed in any of the preceding claims, wherein a pre-setting knob is provided to effect rotary pre-setting of the plunger, which knob is connected to the plunger by a torque limiting coupling.
15. A syringe-operating mechanism comprising an incrementing mechanism as claimed in any of the preceding claims in combination with a means to hold a cartridge of an injectable substance and having a piston engageable by the operating rod whereby a measured dose will be dispensed from the cartridge upon cycling the incrementing mechanism.

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2/6

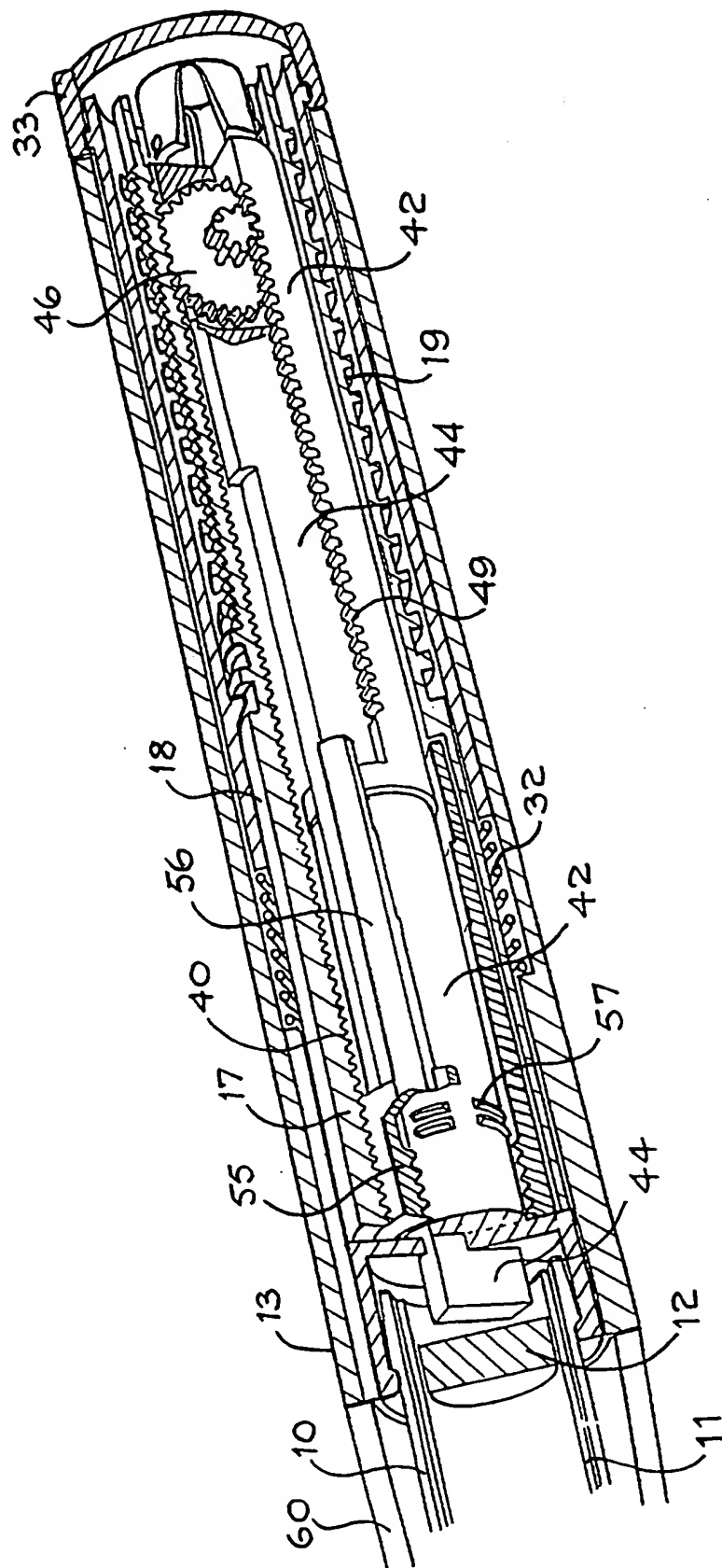


Fig 2

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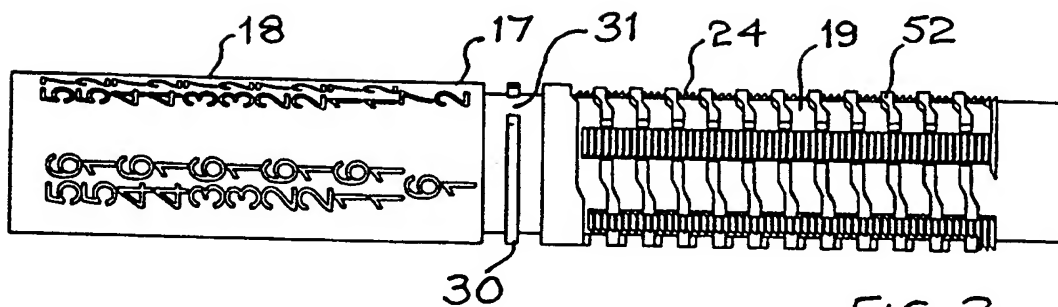


FIG 3

FIG 4A

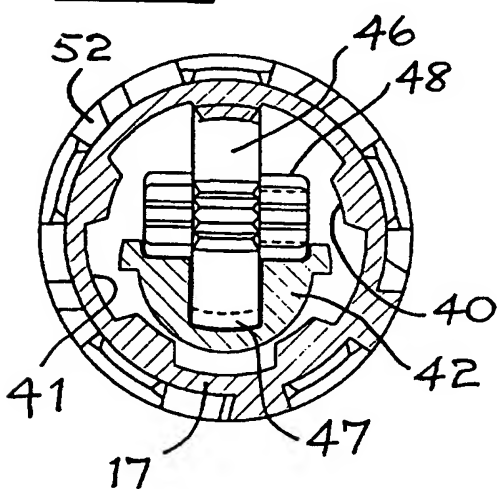


FIG 4B

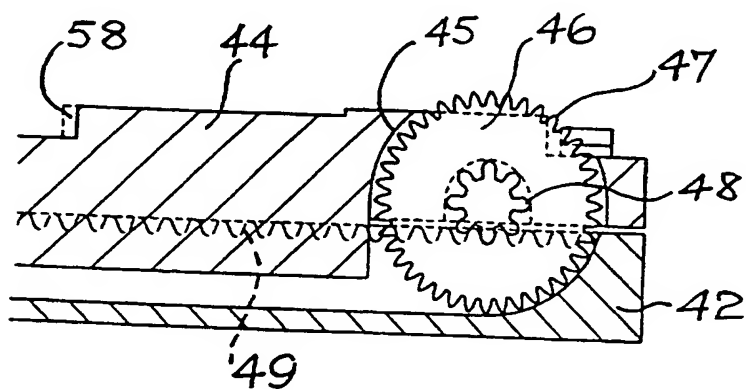
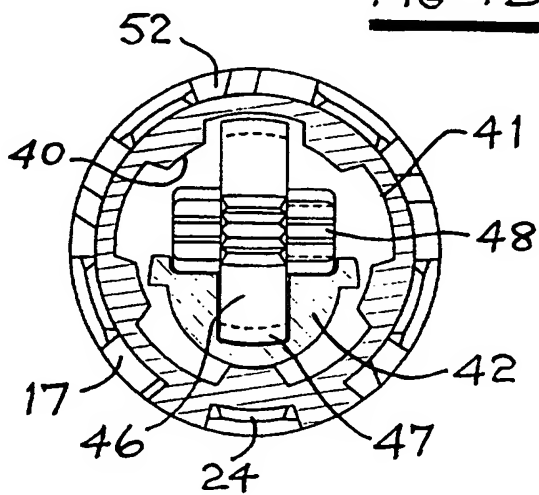
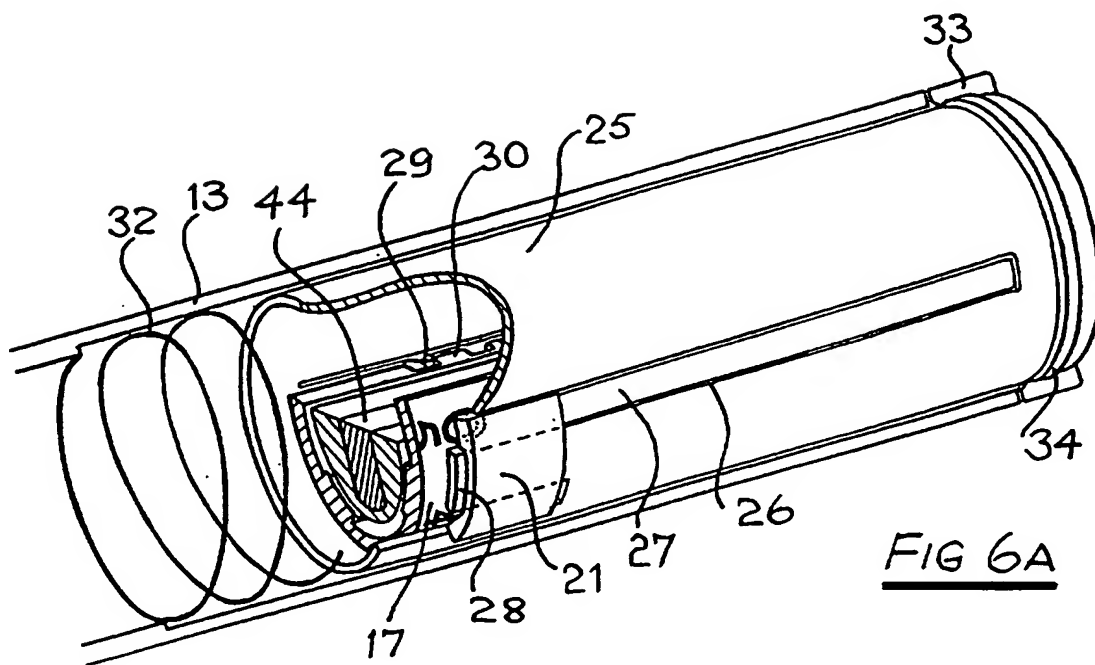
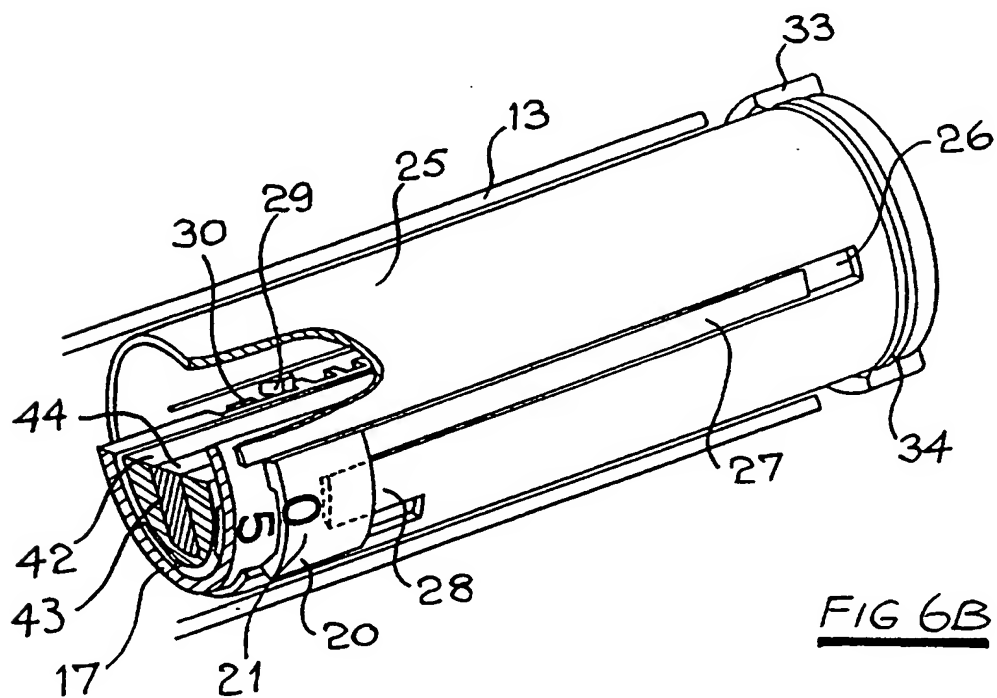


FIG 5

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FIG 6AFIG 6B

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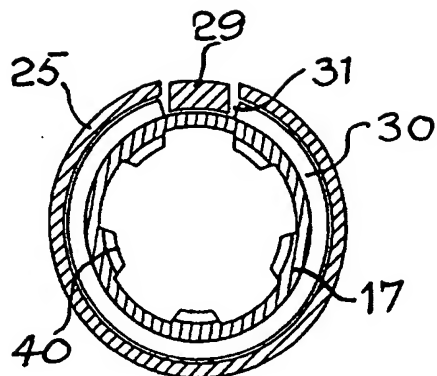


FIG 7A

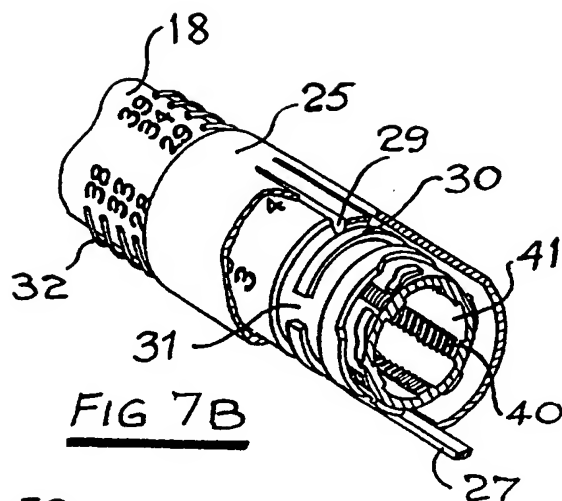


FIG 7B

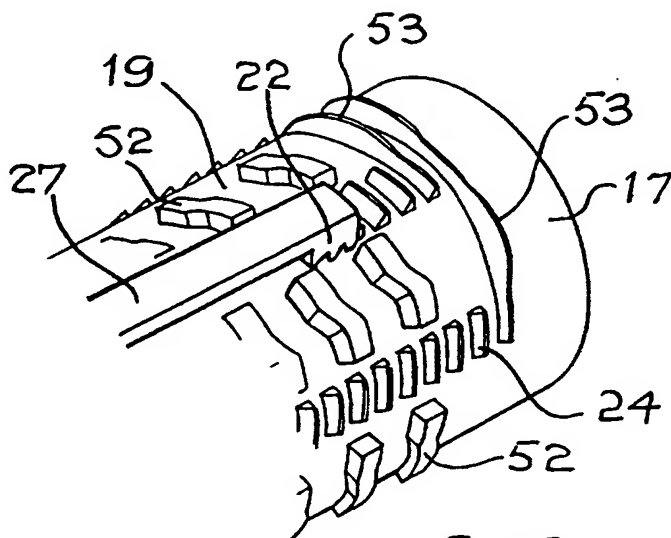


FIG 8

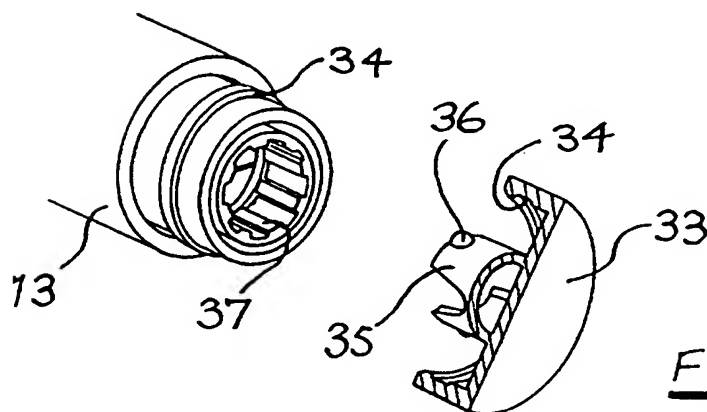


FIG 9

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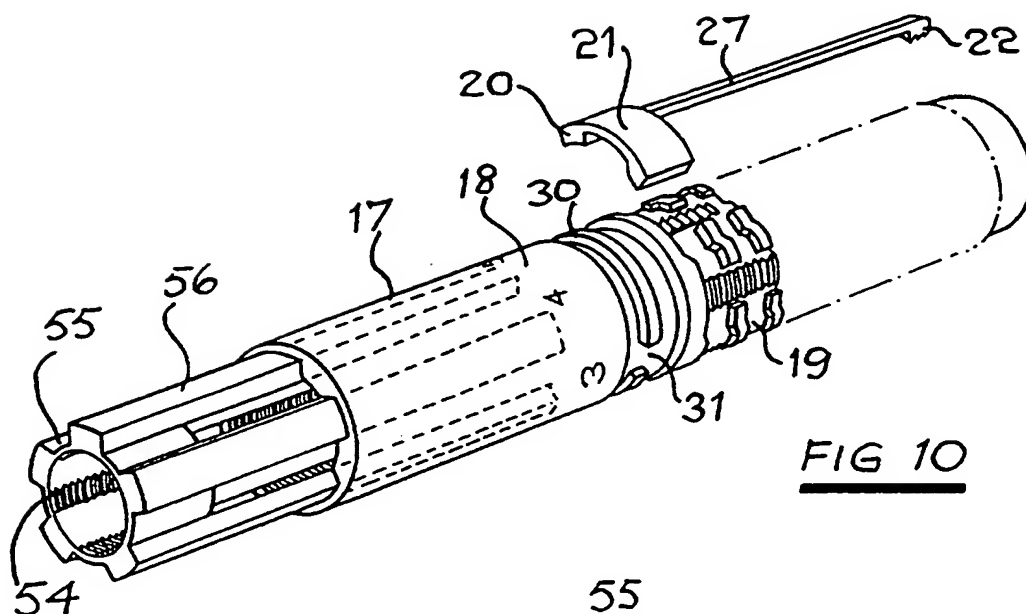


FIG 10

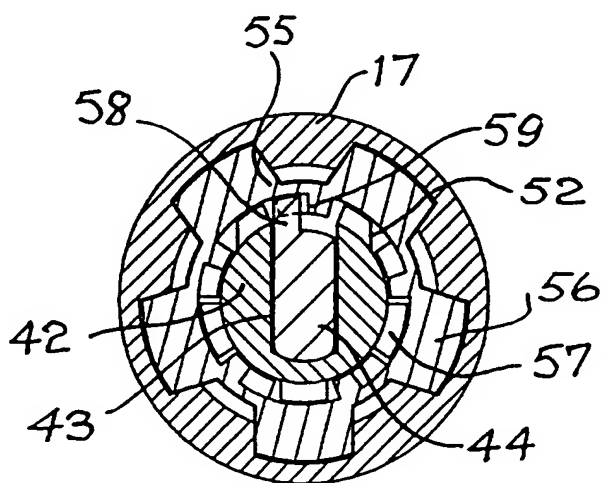


FIG 11

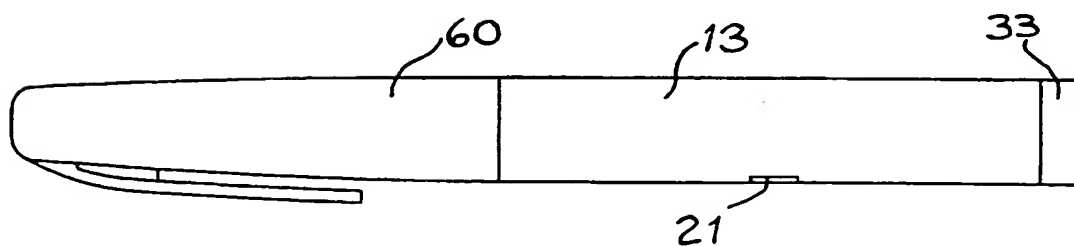


FIG 12

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